

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Donna Loustaunau, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00484

MEMORANDUM OPINION AND ORDER
(*Daubert Motion re: Vladimir Iakovlev, M.D.*)

Pending before the court is the Motion to Exclude Specific-Causation Opinions of Vladimir Iakovlev, M.D. [ECF No. 115] filed by the defendants. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 60,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file general causation *Daubert* motions in the main MDL and specific causation *Daubert* motions, responses, and replies in the individual member cases. To the extent that an expert is both a general and specific causation expert, the parties were advised that they could file a general causation motion in the main MDL 2327 and a specific causation motion in an individual member case. PTO No. 217, at 4.

II. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

In the context of specific causation expert opinions, the Fourth Circuit has held that “a reliable differential diagnosis provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999).

A reliable differential diagnosis typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. at 262 (citations omitted). “A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.” *Id.* at 265. However, an expert’s causation opinions will not be excluded “because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.” *Id.* “The alternative causes suggested by a defendant ‘affect the weight that the jury should give the expert’s testimony and not the admissibility of that testimony,’ unless the expert can offer ‘no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the

sole cause.” *Id.* at 265 (citations omitted).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Ethicon first argues generally that I should exclude Dr. Iakovlev’s opinions because he is unqualified to render them and his methodology is unreliable. However, its first argument fails to specifically show that Dr. Iakovlev is unqualified or his methodology is unreliable. Ethicon’s Motion on this point is **DENIED**.

Ethicon next argues that I should exclude Dr. Iakovlev’s opinions because he neither examined Ms. Loustaunau nor examined explanted mesh from Ms. Loustaunau. However, Dr. Iakovlev did review tissue samples, and I determine that review is sufficient grounds to move forward. To the extent Ethicon believes Dr. Iakovlev’s opinion is deficient, Ethicon may attack that opinion on cross-examination. Ethicon’s Motion on this point is **DENIED**.

Ethicon next argues that I should exclude Dr. Iakovlev’s opinions regarding the clinico-pathological correlation because Dr. Iakovlev is unqualified to render those opinions. However, I determine that Dr. Iakovlev is sufficiently qualified to render those opinions. Ethicon’s Motion on this point is **DENIED**.

Ethicon next argues that I should exclude Dr. Iakovlev’s risk of pain and dyspareunia opinions because they are irrelevant and baseless. However, I find that those opinions are sufficiently relevant and grounded to move forward. To the extent Ethicon believes Dr. Iakovlev’s opinions are deficient, Ethicon may attack those

opinions on cross-examination. Ethicon's Motion on this point is **DENIED**.

Ethicon next argues that I should exclude a number of Dr. Iakovlev's opinions because they are not based on a reliable methodology. However, I find that Dr. Iakovlev's methodology is sufficient to allow his opinions to move forward. To the extent Ethicon believes Dr. Iakovlev's opinions are deficient, Ethicon may attack those opinions on cross-examination. Ethicon's Motion on this point is **DENIED**.

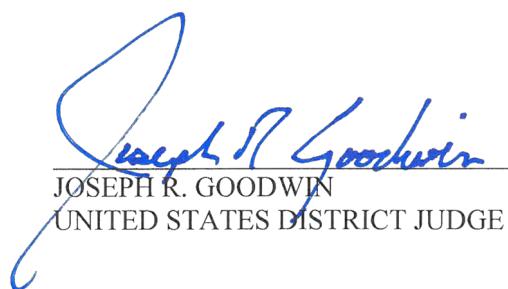
Finally, Ethicon argues that I should prevent Dr. Iakovlev from presenting altered photographs of slides to the jury. However, this part of the Motion is more appropriately dealt with at trial. Ethicon's Motion on this point and any remaining issues are **RESERVED** for trial.

IV. Conclusion

The court **ORDERS** that the Motion to Exclude Specific-Causation Opinions of Vladimir Iakovlev, M.D. [ECF No. 115] is **DENIED in part** and **RESERVED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 29, 2017



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE